J. D. Jackson
TIL
Billingham
Cleveland TS23 IPS
England

FEB 20 1984

Dear J. D. Jackson:

This is in response to your letter of January 11, 1984 in which you requested information on the status of your firm's sunscreen products in relation to the Food and Drug Administration (FDA) regulations. As supplemental information, you submitted a copy of the patent specification describing the composition of several ultraviolet light absorbers presumably marketed by your firm.

FDA is currently reviewing the safety and effectiveness of active ingredients in all OTC drug products. In order to accomplish such a massive task, the FDA established advisory review panels consisting of recognized medical and scientific experts from outside the federal government. One Panel of experts (The Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn and Sunburn Prevention and Treatment Products) reviewed the active ingredients found in OTC sunscreen products. The Panel's recommendations to the FDA concerning the safety and effectiveness of these ingredients were published as a proposed monograph in the FEDERAL REGISTER on August 25, 1978 (copy enclosed). The Panel's discussion of specific sunscreen ingredients recommended testing procedures, and labeling for sunscreen products can be found in the enclosed report.

In response to the Panel's published report, FDA received comments from drug manufacturers, consumers, and experts in the field of sunscreen testing. FDA is currently evaluating the Panel's recommendations and the comments with the intent of developing a tentative final monograph which will include specific sunscreen drug ingredients and labeling. In the tentative final monograph the FDA may accept, reject, or modify the Panel's recommendations but the agency's tentative conclusions will be published in the future. Upon publication of the agency's tentative conclusions, there will be a comment

period to allow interested persons to submit comments and new data before FDA issues a final monograph.

I hope you find this information helpful.

Sincerely yours,

Saul Bader, Ph. D.
Chief, Eye, Ear, Nose, Throat,
and Oral Cavity Drug Monographs Branch
Division of OTC Drug Evaluation
National Center for Drugs and Biologics

Enclosure

cc: HFN-510:DDC-940.1/Reading/Deputy
HFN-513:(sunscreen TFM):Bader/Barry
R/D:EBarry:sam:2/16/84:Rev:2/17/84
Init:SBader:EBarry:2/22/84
F/T:GTrosclair:sam:2/22/84